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PATENT  
Attorney Docket No. 3631-0117P

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: KLYSNER, S. et al. CONF #: 2471  
SERIAL No.: 09/620,586 GROUP: 1644  
FILED: July 20, 2000 EXAMINER: BELYAVSKIY, M.  
FOR: METHOD FOR DOWN-REGULATING GDF-8 ACTIVITY

**RESPONSE TO RESTRICTION REQUIREMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

October 10, 2002

Sir:

In response to the Office Action dated September 9, 2002, the following amendments and remarks are submitted in connection with the above-indicated application.

**AMENDMENTS**

22. (Twice Amended) The method according to claim 19, wherein the GDF-8 polypeptide, the subsequence thereof, or the modified GDF-8 polypeptide optionally has been formulated with a pharmaceutically and immunologically acceptable vehicle and has been formulated with an adjuvant which facilitates breaking of autotolerance to autoantigens, such as an adjuvant selected from the group consisting of an immune targeting adjuvant; an immune modulating adjuvant such as a toxin, a cytokine and a

mycobacterial derivative; an oil formulation; a polymer; a micelle forming adjuvant; a saponin; an immunostimulating complex matrix (an ISCOM matrix); a particle; DDA; aluminum adjuvants; DNA adjuvants;  $\gamma$ -inulin; and an encapsulating adjuvant.

**REMARKS**

1. Prior Response to Restriction Requirement

Applicant has amended claim 22 to remove reference to a "carrier". Applicant has amended the claim language to clarify the claim in response to the comments the Examiner made in paragraph 4 of the last Office Action. As the Examiner may recall, Applicant had elected the claims of Group I and had elected the species without a carrier molecule for search and examination. In paragraph 4(b), the Examiner required the applicant to elect a specific adjuvant as recited in claim 22. The Examiner also noted that Applicant had elected the species without a carrier molecule. Yet, claim 22 recites a "carrier and/or vehicle . . .". The recitation of a carrier used in a formulation is not the same as a carrier molecule. However, to avoid confusion, Applicant has deleted this terminology from the claim.

Applicant also would like to comment on the Examiner's comments in paragraph 4(A) of the last Office Action. The Examiner required Applicant to elect a specific method wherein the immune system is effected by a specific number of copies of the GDF-8 polypeptide or analog. Claim 18 recites that at least 2 copies are coupled to the carrier molecule. As described on page 28 of the Specification, the carrier molecule is mixed with the polypeptide and coupling results. Since one normally couples an unknown number of polypeptides to each carrier, it

would be difficult to recite a specific number of copies actually coupled to a carrier molecule. Applicant would also like to point out that claim 18 should only be of issue if Applicant has elected a species requiring coupling to a species. As noted above, Applicant had elected the claims of Group I and the species without a carrier molecule. Applicant, therefore, does not see a need to specify the specific number of GDF-8 polypeptide or analog coupled to a carrier molecule in claim 18.

## 2. Species Election

The Examiner has indicted that Applicant's prior response filed on July 29, 2002 is not fully responsive. Specifically, the Examiner notes that Applicant had failed to elect a specific SEQ ID NO. as set forth in paragraph 5.4.1 and, if modification by substitution was selected, to specify to position of the substituted amino acid from the species set forth in paragraph 5.4.2.1.

Applicant had previously elected species B (modified by substituting at least one amino acid). Applicant hereby elects SEQ ID NO: 12 to comply with the species election requirement set forth in paragraph 5.4.1 and elects D (residues 49-69) to comply with the species election set forth in paragraph 5.4.2.1.

Examination on the merits and favorable action on the claims in accordance with the above are requested.

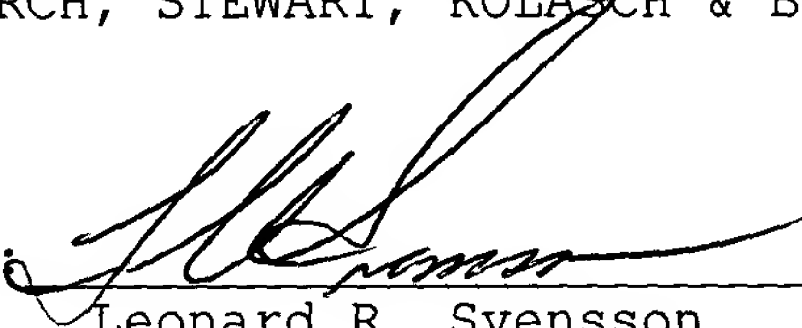
If the Examiner has any questions concerning this application, he is requested to contact Leonard Svensson (Reg. No.: 30,330) the undersigned at (714) 708-8555 in California.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By:

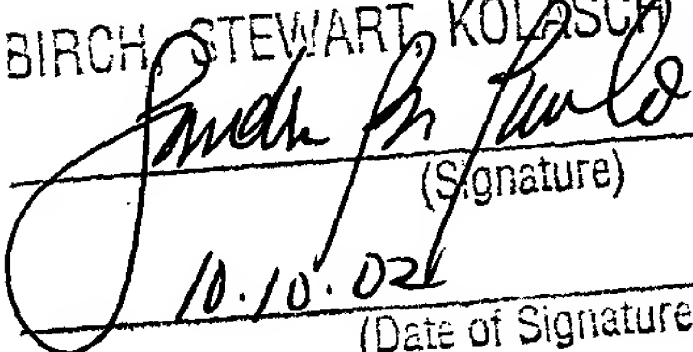
  
Leonard R. Svensson  
Registration No. 30, 330

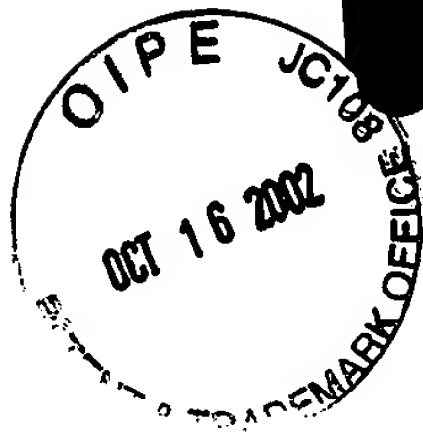
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For: METHOD FOR DOWN-REGULATING GDF-8  
ACTIVITY

LARGE ENTITY TRANSMITTAL FORM

Assistant Commissioner for Patents  
Washington, DC 20231

October 10, 2002

Sir:

Transmitted herewith is a Reply to Restriction/Election Requirement in the above-identified application.

- ☒ The enclosed document is being transmitted via the Certificate of Mailing provisions of 37 C.F.R. § 1.8.
- ☐ Petition for \_\_\_\_\_ ( ) month(s) extension of time pursuant to 37 C.F.R. §§ 1.17 and 1.136(a). \$0.00 for the extension of time.
- ☒ No fee is required.
- ☐ A check in the amount of \$0.00 is enclosed.
- ☐ Please charge Deposit Account No. 02-2448 in the amount of \$0.00. A triplicate copy of this sheet is attached.

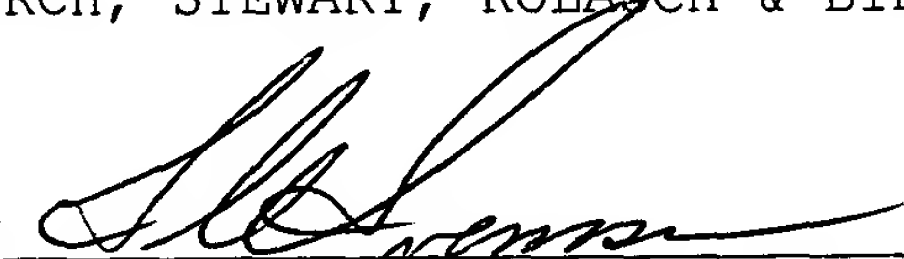
Appl. No. 09/620,586

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Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By



Leonard R. Svensson, #30,330

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3631-0117P

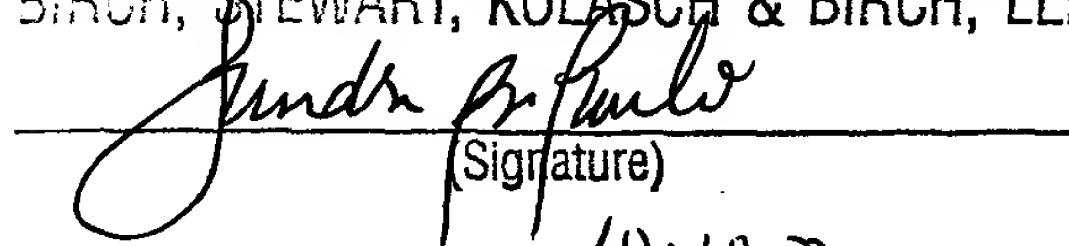
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